

Remarks

Status of the Claims

Claims 1-38 are pending in the application, with claims 1-9, 22-24, 26, 29 and 33 being the independent claims. Claims 3-9, 12-14, 17, 22-25, 30, 31 and 35 have been withdrawn from consideration.

Summary of the Office Action

In the Office Action dated February 17, 2004, the Examiner has made 14 rejections of the claims. Based on the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding rejections and that they be withdrawn.

The Rejection Under 35 U.S.C. § 112, First Paragraph

In the Office Action at pages 3-5, the Examiner has rejected claims 33-34 and 38, under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to the ordinarily skilled artisan that the inventors, at the time the application was filed, had possession of the claimed invention. Applicants respectfully traverse this rejection.

The Examiner contends that the present specification does not provide sufficient information regarding the structures of the claimed vectors such that one of ordinary skill in the art could be expected to prepare them without undue experimentation. Applicants respectfully disagree with these contentions.

Applicants respectfully submit, that with regard to the vectors that do not have their corresponding sequences set forth in the present specification, the ordinarily skilled artisan

would have found sufficient guidance in the drawings and descriptions provided in the present specification for these vectors that would allow them to be prepared without undue experimentation. For example, the ordinarily skilled artisan would have readily recognized that the vector pMAB86 (Figure 99A) is substantially similar to vector pMAB58 (Figure 87) based on the vector maps provided. Taking the map for the pMAB58 vector, and using the sequence (Figures 99B-99D) and vector map provided for pMAB86, the ordinarily skilled artisan would be able to prepare vector pMAB58. Only routine modifications to the vector sequence of pMAB86 are required to generate the pMAB58 vector, and these modifications are clearly illustrated in the pMAB58 vector map.

In light of the foregoing remarks, Applicants respectfully submit that an ordinarily skilled artisan would recognize that the inventors, at the time the application was filed, had full possession of the claimed invention. Hence, Applicants respectfully request that the rejection of claims 33-34 and 38, under 35 U.S.C. § 112, first paragraph, be reconsidered and withdrawn.

The Rejections Under 35 U.S.C. § 112, Second Paragraph

In the Office Action at pages 5-9, the Examiner has rejected claims 1, 2, 10-11, 15-16, 18-21, 26-29, 32 and 36-38, under 35 U.S.C. § 112, second paragraph, for allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Applicants respectfully traverse these rejections.

A. The Rejection of Claims 1, 2, 10-11, 15-16, 18-21 and 36-38.

In the Office Action at page 6, the Examiner has rejected claims 1, 2, 10-11, 15-16, 18-21, and 36-38, under 35 U.S.C. § 112, second paragraph, alleging that the phrase "an ___ nucleotide sequence as set forth in Figure 9," does not clearly limit the claims to a particular sequence. Applications respectfully traverse this rejection.

Applicants respectfully submit that the ordinarily skilled artisan would readily recognize that the phrase "an ___ nucleotide sequence as set forth in Figure 9," clearly refers to the specific nucleotide sequences set forth in Figure 9. Hence, Applicants respectfully request that this rejection be reconsidered and withdrawn.

B. The Rejection of Claims 1, 10-11, 15-16, 18-21 and 36-38.

In the Office Action at page 6, the Examiner has rejected claims 1, 10-11, 15-16, 18-21 and 36-38, under 35 U.S.C. § 112, second paragraph, alleging that it is unclear whether the phrases "polynucleotide complementary thereto" and "a mutant, fragment or derivative thereof" refer to each of the previously recited sequences, or to only the sequence immediately prior to the recitation. Applicants respectfully traverse this rejection.

Applicants respectfully submit that the ordinarily skilled artisan would readily recognize that the phrases "polynucleotide complementary thereto" and "a mutant, fragment or derivative thereof" clearly refer to any of the nucleotide sequences recited in claim 1. Hence, Applicants respectfully request reconsideration and withdrawal of this rejection.

C. The Rejections of Claim 11

In the Office Action at pages 6-7, the Examiner has rejected claim 11, under 35 U.S.C. § 112, second paragraph, alleging that it is unclear how or whether the claim is intended to further limit the sequences of claim 10, or the transcriptional regulatory sequences. The Examiner further alleges that there is insufficient antecedent basis for the limitation "said transcriptional regulatory sequence." Applicants respectfully traverse these rejections.

Applicants respectfully submit that the ordinarily skilled artisan would readily understand that claim 11 further limits the transcriptional regulatory sequences recited in claim 10 to promoters, enhancers or repressors. Applicants further submit that there is sufficient antecedent basis for the phrase "said transcriptional regulatory sequence" in claim 10. Hence, Applications respectfully request reconsideration and withdrawal of these rejections.

D. The Rejection of Claims 15-16, 18 and 37

In the Office Action at page 7, the Examiner has rejected claims 15-16, 18 and 37, under 35 U.S.C. § 112, second paragraph, alleging that it is unclear whether the recitation "linked to a target-specific nucleotide sequence useful in amplifying said target nucleotide sequence" in claim 15 refers back to and limits the "primer nucleic acid molecule" or the "target nucleotide sequence." The Examiner further alleges that it is unclear whether the phrase "linked to a target-specific nucleotide sequence useful in amplifying said target nucleotide sequence" limits only the "portion thereof" of applies to any primer encompassed by the claim. Applicants respectfully traverse this rejection.

Applicants respectfully submit that the ordinarily skilled artisan would readily recognize that the phrase "linked to a target-specific nucleotide sequence useful in amplifying said target nucleotide sequence," limits *both* the isolated nucleic acid molecule of claim 1 *and* a portion thereof. Hence, Applicants respectfully request that this rejection be reconsidered and withdrawn.

E. The Rejection of Claim 16

In the Office Action at page 8, the Examiner has rejected claim 16, under 35 U.S.C. § 112, second paragraph, alleging that it is indefinite. Applicants respectfully traverse this rejection.

Applicants respectfully submit that the ordinarily skilled artisan would readily understand that the phrase "the sequence shown in Figure 9" as recited in claim 16 refers to the *attB1* nucleotide sequence shown in Figure 9. Hence, reconsideration and withdrawal of this rejection are respectfully requested.

F. The Rejections of Claims 26-28 and 36

In the Office Action at page 8, the Examiner has rejected claims 26-28 and 36, under 35 U.S.C. § 112, second paragraph, alleging that these claims are indefinite. Applicants respectfully traverse these rejections.

Applicants respectfully submit that the ordinarily skilled artisan would readily recognize that the phrase "its core region" refers to the one or more *att* recombination sites. Furthermore, Applicants respectfully submit that the ordinarily skilled artisan would readily recognize that the phrase "said recombination site" refers to the one or more *att*

recombination sites. Applicants respectfully request reconsideration and withdrawal of this rejection.

G. The Rejections of Claims 27 and 28

In the Office Action at page 8, the Examiner has rejected claims 27 and 28, under 35 U.S.C. § 112, second paragraph, alleging that these claims are indefinite. Applicants respectfully traverse these rejections.

Applicants respectfully submit that there is sufficient antecedent basis for the phrases "said mutation" and "the seven basepair overlap region of said core region of said recombination site" in claim 27. Applicants also respectfully submit that there is sufficient antecedent basis for the phrase "the consensus sequence" in claim 28. Hence, Applicants respectfully request reconsideration and withdrawal of these rejections.

H. The Rejections of Claims 29 and 32

In the Office Action at pages 8-9, the Examiner has rejected claims 29 and 32, under 35 U.S.C. § 112, second paragraph, alleging that it is unclear whether "its core region" refers to the isolated nucleic acid molecule or to the one or more *att* recombination sites. The Examiner further alleges that there is insufficient antecedent basis for the term "said mutated *att* recombination site." Applicants respectfully traverse these rejections.

Applicants respectfully submit that the phrase "its core region" is not indefinite as the ordinarily skilled artisan would readily recognize that this phrase refers to the one or more mutated *att* recombination sites. Applicants further submit that that the term "said mutated

att recombination sites" has sufficient antecedent basis. Applicants respectfully request reconsideration and withdrawal of these rejections.

The Rejection Under 35 U.S.C. § 102(b) Over Hartley

In the Office Action at pages 9-10, the Examiner has rejected claims 1-2, 10-11, 15-16, 18-21, 26-29 and 36-38, under 35 U.S.C. § 102(b) as being allegedly anticipated by Hartley *et al.* (WO 96/40724; hereinafter "Hartley"). Applicants respectfully traverse this rejection.

Applicants respectfully disagree with the Examiner's contentions and conclusions. Applicants respectfully request reconsideration and withdrawal of the rejection of claims 1-2, 10-11, 15-16, 18-21, 26-29 and 36-38, under 35 U.S.C. § 102(b) over Hartley.

Conclusion

All of the stated grounds of rejection have been properly traversed. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding rejections and that they be withdrawn.

Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

A handwritten signature in black ink, appearing to read "Brian J. Del Buono", with a long horizontal stroke extending to the right.

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